

K043179

FEB - 8 2005

510(k) Summary

Date Prepared: November 12, 2004

Submitter: Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person: Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: Select 3D™ Arterial Cannula

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification: Class II

Predicate Devices:
Select 3D™ Arterial Cannula
22 Fr.
K013013, K033416

Device Description:

The Select 3D™ Arterial Cannulae both have clear flexible, thin wall wire-wound PVC bodies with angled, beveled tips. The proximal end of the cannula includes a 3/8" (0.95 cm) vented or non-vented connector with a peel cap. The vented connector allows air to be vented from the cannula before connection to the perfusion line.

The Select 3D™ Arterial Cannula tip has three integrated flutes which help diffuse and disperse blood flow. The cannula body features a tip orientation line indicating direction of the cannula tip during cannulation. Overall cannula length is 11.5" (29.2 cm). The new sizes are 18 and 20 Fr. The Cannulae are available uncoated or with a Carmeda® Coating.

Indication for Use

These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Comparison to Predicate Device

The predicate devices are Select 3D™ Arterial Cannulae with the same design characteristics and indications for use. The predicate cannulae had identical design characteristics and materials. The new cannulae differ only in diameter from the predicates.

Summary of Performance Data

In vitro dimensional and functional testing was used to establish the performance characteristic of the new device. The biocompatibility, sterilization, and packaging are not affected by the changes in the device. Accelerated aged dimensional and functional testing was performed as well as flow and hemolysis characterization. The ability to adequately Carmeda® Coat the devices was also tested. All testing passed.

Conclusion

Medtronic Perfusion Systems has demonstrated that the modified Select 3D™ Cannulae (18 and 20 Fr.) are substantially equivalent to the predicate devices based upon design, test results, and indications for use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2005

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Boulevard
Brooklyn Park, MN 55428

Re: K043179
Select 3D™ Arterial Cannula, 18 and 20 Fr.
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: January 6, 2005
Received: January 11, 2005

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

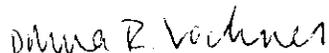
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043179

Device Name: **Select 3D™ Arterial Cannula, 18 and 20 Fr.**

Indications For Use:

These cannulae are intended for use in perfusion of the ascending aorta during short term (6 hours or less) cardiopulmonary bypass.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Lockner
(Division Sign-Off)
Division of Cardiovascular Devices

Device Number K043179